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10/037,307	12/31/2001	Simon M. Furnish	InFraReDx-14	4515

7590

03/04/2004

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35 Central Street  
Manchester, MA 01944

EXAMINER
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JAIN, RUBY

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/037,307

Applicant(s)

FURNISH, SIMON M.

Examiner

Ruby Jain

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: the U.S. Patent Application Number on page 1 of the specification needs to be completed.  
  
Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

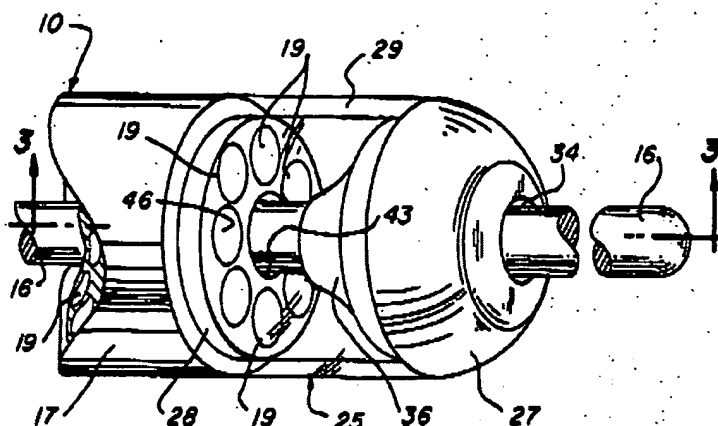
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 8, 10, 13, 14, 19, 24, ~~38-43~~ are rejected under 35 U.S.C. 102(b) as being anticipated by Davies U.S. Patent No. 4,672,961.

Regarding claims 1, 3, 10, 38, 39, and 40, Davies discloses a catheter tip apparatus arranged in a catheter for delivery and collection of a light energy signal comprising an elongated housing having a longitudinal axis and a plurality of annularly disposed elongated grooves on an internal surface of the housing (19), a flexible light energy-bearing optical fibers, longitudinally spaced apart from each other, arranged in each of the grooves (column 2, lines 12-23), each of the optical fibers having a spaced-apart light transmissive communication with the body tissue (column 2, lines 12-23) and (Figure 2).



**Fig\_2**

Regarding claims 4, 5, 13, 14, 24, 41, and 43, Davies discloses wherein each of the light bearing optical fibers has a light re-directing member in its light path, which is arranged distally adjacent to the face end of each of the fibers and is longitudinally displaceable and convex in shape (36). The light re-directing member is an angled reflective annular surface or arcuate configuration (column 2, lines 1-68). The reflector comprises of an independent reflective surface arranged distally adjacent to the face end of each fiber in an annular array (Figure 2).

Regarding claims 6 and 8, Davies discloses wherein the housing has a longitudinally directed bore arranged centrally therethrough with an elongated guidewire (Figure 2 and column 2, lines 1-68).

Regarding claim 19, Davies discloses wherein the housing includes a proximal portion of reduced diameter with respect to the housing containing the grooves (Figure 2).

Regarding claim 42, Davies discloses wherein the light fibers collect light energy, which is wider than the light energy delivered to the body tissue (column 2, lines 29-68).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 1 above, and further in view of Barlow et al. U.S. Patent No. 5,456,259.

Regarding claims 2 and 11, Davies discloses wherein the grooves are disposed on an internal surface of the housing. Davies does not disclose wherein the grooves are disposed on an external surface of the housing and have a ledge at the distal end thereof to provide an abutment to an energy-bearing member disposed within the grooves.

Barlow discloses 64 radially equally spaced grooves, on the external surface of the housing, running axially of the annulus and parallel to its axis. Between each pair of adjacent slots is a transducer element. At the bottom of each groove is an abutment. (Figure 2 and column 5, lines 24-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the grooves are disposed on an external surface of the housing, as per the teachings of Barlow into the teachings of Davies, because the invention would perform equally well with either the grooves disposed on an internal surface or an external surface. It would have been an obvious matter of design choice to have the grooves placed on the external surface of the housing. Furthermore, abutments are inherent in any groove because that is the way the grooves are constructed and characterized.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claims 1 above, and further in view of Murphy-Chutorian et al. U.S. Patent No. 4,832,023.

Regarding claim 12, Davies discloses a catheter tip apparatus arranged in a catheter for delivery and collection of a light energy signal comprising an elongated housing having a longitudinal axis and a plurality of annularly disposed elongated grooves on an internal surface of the housing (19) ((column 2, lines 12-23) and (Figure 2)). Davies does not disclose wherein the grooves are dissimilar in axial length.

Murphy-Chutorian discloses wherein the grooves are dissimilar in axial length (Figure 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the grooves are dissimilar in axial length because the axial length of the grooves does not change its function. Varying

sized grooves may be desired if different size fibers are utilized. But the grooves are just a structural feature that does not change the catheter's function.

5. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claims 1 above, and further in view of Wach et al. U.S. Patent No. 5,953,477.

Regarding claims 7 and 9, Davies discloses wherein the housing comprises of a longitudinally displaceable central lumen extending therethrough (Figure 2). Davies does not disclose wherein the central lumen has an elongated light signal fiber arranged therein.

Wach discloses where in the central lumen has an elongated light fiber arranged therein (Figures 27 A, B, and C).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the central lumen has an elongated light signal fiber arranged therein, as per the teachings of Wach into the teachings of Davies, because the invention would perform equally well with either the fibers annularly disposed or with fibers annularly disposed with a central fiber. Furthermore, it would have been an obvious matter of design choice to further have a fiber in the central lumen.

6. Claims 15, 16, and 23, are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 13 above, and further in view of Sinofsky U.S. Patent No. 4,950,266.

Regarding claims 15, 16, and 23, Davies discloses wherein each of the light bearing optical fibers has a light re-directing member in its light path, which is arranged distally adjacent to the face end of each of the fibers and is longitudinally displaceable and convex in shape (36). The light re-directing member is an angled reflective annular surface or arcuate configuration (column 2, lines 1-68). Davies does not disclose wherein there are a plurality of reflective surfaces, one for each fiber, where each reflective surface is dissimilar in surface characteristics, disposed at a certain angle, carries different signals, and is disposed at differing longitudinal locations.

Sinofsky discloses a four-fiber catheter comprising four mirrors (60, 62, 64, and 68) arranged at a 45-degree angle and disposed at differing locations. The first mirror has a 25% reflective surface and directs  $\frac{1}{4}$  of the total energy, mirror 62 is a 33% reflector which directs  $\frac{1}{4}$  of the total energy, mirror 64 is a 50% reflector which directs  $\frac{1}{4}$  of the total laser output, and the last mirror is a 100% reflector which directs the remaining  $\frac{1}{4}$  of the total energy. Mirrors and lenses are conventional devices with different arcuate dimensions (column 7, lines 35-68 and Figure 8).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein there are a plurality of reflective surfaces, one for each fiber, where each reflective surface is dissimilar in surface characteristics, disposed at different angles, carries different signals, and is disposed at



differing longitudinal locations, as per the teachings of Sinofsky into the teachings of Davies, because the plurality of reflective surfaces does not change the function of one reflective surface. It would be obvious to include a plurality of reflective surfaces with varying characteristics depending on what output filtering and reflecting result is desired.

7. Claims 17, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 13 above, and further in view of Wach et al. U.S. Patent No. 5,953,477.

Regarding claim 17, Davies discloses wherein each of the light bearing optical fibers has a light re-directing member in its light path, which is arranged distally adjacent to the face end of each of the fibers and is longitudinally displaceable and convex in shape (36). The light re-directing member is an angled reflective annular surface or arcuate configuration (column 2, lines 1-68). Davies does not disclose wherein the light re-directing member on at least one of the fibers comprises of a ball.

Regarding claims 20 and 21, Davies does not disclose wherein the reflective surface comprises of an annular array of lensed prisms arranged distally adjacent to the end of the fibers.

Wach discloses wherein the light re-directing member on at least one of the fibers comprises of a ball. Furthermore, Wach discloses wherein the reflective element may be a lens or a prism with contour on its internally reflective surface (column 75, lines 6-34).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the light re-directing member on at least one of the fibers comprises of a ball or lensed prism, as per the teachings of Wach into the teachings of Davies, because the shape or type of re-directing or reflecting member does not change the function of re-directing a beam of light.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 4 above, and further in view of Lemelson U.S. Patent No. 6,321,106.

Regarding claim 18, Davies discloses wherein each of the light bearing optical fibers has a light re-directing member in its light path, which is arranged distally adjacent to the face end of each of the fibers and is longitudinally displaceable and convex in shape (36). The light re-directing member is an angled reflective annular surface or arcuate configuration (column 2, lines 1-68). Davies does not disclose wherein the reflective surface is arranged at an angle of about 45 degrees with respect to the longitudinal axis.

Lemelson discloses wherein mirror (408) is tilted at approximately at 45-degree angle (Figure 25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the reflective surface is arranged at an angle of about 45 degrees with respect to the longitudinal axis, as per the teachings of Lemelson into the teachings of Davies, because the angle of the reflecting

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member does not change the function of it. Light will just possibly be directed in a different direction.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 13 above, and further in view of Dickinson et al. U.S. Patent No. 5,465,726.

Regarding claim 22, Davies discloses wherein each of the light bearing optical fibers has a light re-directing member in its light path, which is arranged distally adjacent to the face end of each of the fibers and is longitudinally displaceable and convex in shape (36). The light re-directing member is an angled reflective annular surface or arcuate configuration (column 2, lines 1-68). Davies does not disclose wherein the reflective surface is a conical reflector disposed adjacent to the grooves.

Dickinson discloses a conically shaped reflecting surface located co-axially with respect to the disk-like piezoelectric elements (column 2, lines 29-65).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the reflective surface is a conical reflector disposed adjacent to the grooves, as per the teachings of Dickinson into the teachings of Davies, because the shape of the reflector does not change the function of it. As a matter of design choice, any convex, concave, aspherical, parabolic shaped reflective surface would optimally direct beam light.

10. Claims 25-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies, and further in view of Mueller et al. U.S. Patent No. 6,156,029.

Regarding claim 25, Davies discloses a catheter tip apparatus arranged in a catheter for delivery and collection of a light energy signal comprising an elongated housing having a longitudinal axis and a plurality of annularly disposed elongated grooves on an internal surface of the housing (19), a flexible light energy-bearing optical fibers, longitudinally spaced apart from each other, arranged in each of the grooves (column 2, lines 12-23), each of the optical fibers having a spaced-apart light transmissive communication with the body tissue (column 2, lines 12-23) and (Figure 2). Davies does not disclose wherein each fiber in each of the grooves comprises of an annular array of axially disposed light bearing fibers.

Mueller disclose wherein each fiber in each of the grooves comprises of an annular array of axially disposed light bearing fibers (Figure 2D).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein each fiber in each of the grooves comprises of an annular array of axially disposed light bearing fibers, as per the teachings of Mueller into the teachings of Davies, because the quantity of light bearing fibers does not change the overall function of the catheter.

Regarding claims 26, 27, and 37, Davies discloses wherein each of the light bearing optical fibers has a light re-directing member in its light path, which is arranged distally adjacent to the face end of each of the fibers and is longitudinally displaceable

and convex in shape (36). The light re-directing member is an angled reflective annular surface or arcuate configuration (column 2, lines 1-68). The reflector comprises of an independent reflective surface arranged distally adjacent to the face end of each fiber in an annular array (Figure 2).

Claims 28, 29, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 25 above, in view of Mueller, and further in view of Wach et al. U.S. Patent No. 5,953,477.

Regarding claims 28, 29, and 36, Davies does not disclose wherein the reflective surface comprises of an annular array of lensed prisms arranged distally adjacent to the end of the fibers.

Wach discloses wherein the reflective element may be a lens or a prism with contour on its internally reflective surface (column 75, lines 6-34).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the light re-directing member on at least one of the fibers comprises of a lensed prism, as per the teachings of Wach into the teachings of Davies in view of Mueller, because the shape or type of re-directing or reflecting member does not change the function of re-directing a beam of light.

Claims 30-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 25 above, in view of Mueller, and further in view of Sinofsky U.S. Patent No. 4,950,266.

Regarding claims 30-32 and 35, Davies discloses wherein each of the light bearing optical fibers has a light re-directing member in its light path, which is arranged distally adjacent to the face end of each of the fibers and is longitudinally displaceable and convex in shape (36). The light re-directing member is an angled reflective annular surface or arcuate configuration (column 2, lines 1-68). Davies does not disclose wherein there are a plurality of reflective surfaces, one for each fiber, where each reflective surface is dissimilar in surface characteristics, disposed at a certain angle, carries different signals, and is disposed at differing longitudinal locations.

Sinofsky discloses a four-fiber catheter comprising four mirrors (60, 62, 64, and 68) arranged at a 45-degree angle and disposed at differing locations. The first mirror has a 25% reflective surface and directs  $\frac{1}{4}$  of the total energy, mirror 62 is a 33% reflector which directs  $\frac{1}{4}$  of the total energy, mirror 64 is a 50% reflector which directs  $\frac{1}{4}$  of the total laser output, and the last mirror is a 100% reflector which directs the remaining  $\frac{1}{4}$  of the total energy. Mirrors and lenses are conventional devices with different arcuate dimensions (column 7, lines 35-68 and Figure 8).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein there are a plurality of reflective surfaces, one for each fiber, where each reflective surface is dissimilar in surface characteristics, disposed at different angles, carries different signals, and is disposed at differing longitudinal locations, as per the teachings of Sinofsky into the teachings of Davies in view of Mueller, because the plurality of reflective surfaces does not change the function of one reflective surface. It would be obvious to include a plurality of

reflective surfaces with varying characteristics depending on what output filtering and reflecting result is desired.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claims 25 above, in view of Mueller, and further in view of Wach et al. U.S. Patent No. 5,953,477.

Regarding claims 33 and 34, Davies discloses wherein the housing comprises of a longitudinally displaceable central lumen extending therethrough (Figure 2). Davies does not disclose wherein the central lumen has an elongated light signal fiber arranged therein.

Wach discloses where in the central lumen has an elongated light fiber arranged therein (Figures 27 A, B, and C).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose wherein the central lumen has an elongated light signal fiber arranged therein, as per the teachings of Wach into the teachings of Davies in view of Mueller, because the invention would perform equally well with either the fibers annularly disposed or with fibers annularly disposed with a central fiber. Furthermore, it would have been an obvious matter of design choice to further have a fiber in the central lumen.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruby Jain whose telephone number is (703) 605-4250. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RJ

February 17, 2004

  
**DENNIS W. RUHL**  
**SUPERVISORY PATENT EXAMINER**